

REMARKS

1. The Amendments and the Support Therefor

No claims have been canceled, three new claims (82-84) have been added, and claim 62 has been amended to leave claims 51, 53, 55-64, 67, 68, and 70-84 in the application. Payment for any newly-submitted claims in excess of the amount previously paid for should accompany this Response, as per 37 CFR §1.16(b)-(d), with the fee due being calculated as follows:

FEE CALCULATION

| For | Already Paid | No. Extra | Rate (SMALL ENTITY) | Fee (SMALL ENTITY) |
|--------------------|--------------|-----------|------------------------------|-----------------------------|
| Total Claims | 29 - 26 = | 3 | x \$26 = | \$78 |
| Independent Claims | 4 - 4 = | 0 | x \$110 = | \$0 |
| | | | Total: | \$78 |

No new matter has been added by the amendments or new claims, wherein:

- *Independent claim 62* has been amended to address the issues with antecedent basis discussed in Section 3 below;
- *Claim 82:* Finds support at (for example) claim 61;
- *Claims 83-64:* Finds support at (for example) FIG. 1.

Further comments regarding the new claims are set out below at Section 8.

2. Sections 1-2 of the Office Action: Rejections of Claims 76-78 Under 35 USC §101

Kindly reconsider and withdraw these rejections, which contend that these claims do not comply with §101 “because they claim an artery, an unpatentable part of the human body, as structural part of the invention.” These claims recite the fixator within its operating environment, i.e., within an artery or the like, and since the recited matter is not naturally occurring – it can only arise through human activity – the claims do in fact comply with §101. As noted, for example, in *SmithKline Beecham Corp. v. Apotex Corp.*, 74 USPQ2d 1398, 1418 (Fed. Cir. 2005), “human-made, or synthetic, products or processes are patentable, while products and processes of nature are not.” Thus, as noted (for example) in MPEP 2105, naturally-occurring matter (such as a human body part alone) may be non-statutory under §101. However, there is no prohibition on claims to a combination of a device *with* a human body part, as recited here. If the rejection is maintained, kindly provide cases, MPEP provisions, or the like supporting the rejections, since the

claimed matter is not known to be contrary to §101.

3. Sections 3-4 of the Office Action: Rejection of Claims 62, 68, 70-72 and 81 under 35 USC §112(2)

Kindly reconsider and withdraw the rejections of claim 62. Regarding the assertion that “the ‘artery wall,’ an unpatentable part of the human body, is essentially claimed as structural part of the invention”, this is not a proper basis for a §112(2) rejection: it is plain that this recitation is clear and definite, such that any reader can determine what is and is not encompassed by this recitation, and thus this recitation is in agreement with 35 USC §112(2). See MPEP 2173 *et seq.*, particularly MPEP 2173.02 (“Clarity and Precision”); also see the foregoing Section 2 of this Response.

Regarding the assertions that it is uncertain whether the catheter is part of the claimed invention, and that “the central section” lacks antecedent basis, claim 62 has been amended to clarify that the catheter is *not* part of the claimed invention, and to provide antecedent basis for “the central section.”

Regarding claim 68, please note that the preamble and clause b provide that the “fixator compris[es] elongated members . . . being connected between their first and second parts”. Thus, the recitation of “the connection between the elongated members” has antecedent basis.

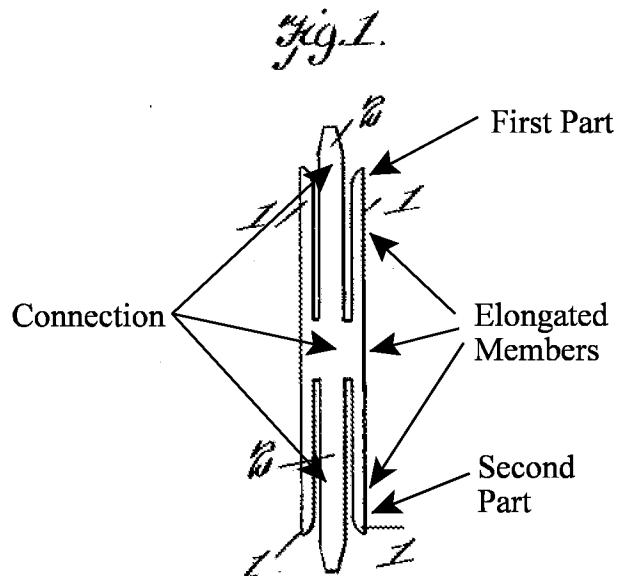
4. Sections 5-6 of the Office Action: Rejection of Claims 68, 71, 72 and 81 under 35 USC §102(b) in view of U.S. Patent 1,036,229 to Harrild

Harrild is directed to an improved dowel which provides advantages over an ordinary dowel (i.e., a simple rod) when used for attaching opposing pieces of wood. The *Harrild* dowel has a center piece 2 similar to a conventional dowel, which can be struck to drive it into a piece of wood. Side spurs 1 angle off of the center piece 2 when the dowel is driven into wood so that the spurs 1 firmly anchor the center piece 2 in the wood. To anchor one piece of wood to another, the opposing ends of the dowel must be embedded in opposing pieces of wood.

The rejection of **claim 68** recites that:

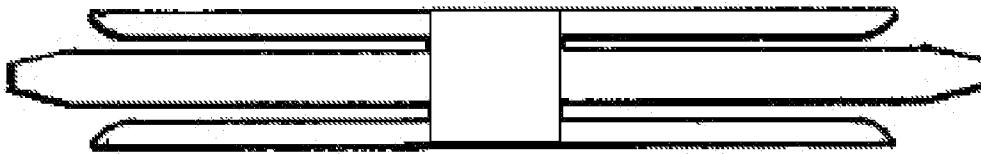
Harrild discloses, at least in figures 1 and 2, a fixator comprising elongated members (1), each elongated member extending between first and second parts, where the first and second parts (the opposing end portions) are sharpened, where each elongated member has an open configuration (see fig. 1) with first and second parts that are distant and aligned along a common axis, first and second parts adjacently situated with their lengths in abutment (at central portions) and substantially coaxial, and where the fixator has a substantially uniform cross-sectional area as it extends from its first parts to its second parts; and a retaining configuration (see fig. 2), where the first and second parts are closely spaced, where the first and second parts extend from a connection (2) between the elongated members, where the each elongated member is biased or bent towards the retaining configuration (after being driven into a medium), where the first and second parts define terminal ends, where the fixator has a substantially uniform cross-sectional area between the nonsharpened portions of the first and second parts when the elongated members are in the open configuration, and where the fixator, when in the retaining configuration is shorter along a direction aligned along the linear axis (i.e., parallel to linear axis) than when in the open configuration.

This is understood to assert that *Harrild* has the following structure:



Claim 68 does not read on *Harrild* under any reasonable construction of the claim. Note that claim 68, clause i. recites that “only the first and second parts extend from the connection between the

elongated members.” *Harrild*’s first and second parts – the only parts that move between the recited open and retaining configurations – are connected *only* by the shaded portion shown below, and this shaded portion plainly has *Harrild*’s dowels / center pieces 2 extending therefrom. Thus, it cannot be said that *Harrild* meets the recitation of claim 68 that “only the first and second parts extend from the connection between the elongated members.”



The rejection appears to assert that the *entireties* of *Harrild*’s center pieces 2 constitute the recited “connection.” As stated at pages 6-7 of the Office Action:

Harrild indeed discloses that only first and second parts extend from a connection between the elongate members, where the connection includes element 2, which has centrally-located portions integrated with the first and second parts.

It is accepted that during examination, the USPTO must interpret the claims using their broadest reasonable interpretation (MPEP 2111). Words in a claim are therefore given their plain meaning unless a contrary definition is provided in the specification (MPEP 2111.01). However, the Office Action’s interpretation of “connection” as encompassing the entireties of the lengths of the opposing center pieces 2 is an overbroad and unreasonable construction of claim 68: it cannot fairly be said that any portions of *Harrild*’s center pieces 2 apart from the shaded portion above constitute the recited “connection,” since the portions of *Harrild*’s center pieces 2 extending from the shaded portion perform no “connection” whatsoever, and would not be regarded by any ordinary artisan as constituting the recited “connect[ion] between the[] first and second parts” as recited in clause b.

Further, clause ii. of claim 68 recites that “the elongated members, when in their open configurations, have their first parts adjacently situated in abutment and their second parts adjacently situated in abutment.” The elongated members of *Harrild* are shown above in their open configurations, and their first parts are plainly not adjacently situated in abutment, nor are their second parts adjacently situated in abutment. Rather, the first parts are spaced from each other by *Harrild*’s center piece 2 (and the first parts are also spaced from *Harrild*’s center piece 2), and the

second parts are spaced from each other by *Harrild*'s center piece 2 (and the second parts are also spaced from *Harrild*'s center piece 2). Note the gaps between each adjacent first part, center piece, and second part.

Further, it would not be obvious to modify *Harrild* to remove *Harrild*'s center piece 2 to meet the claimed structure: no ordinary artisan would contemplate modifying *Harrild* to meet these claims because *Harrild*'s center piece 2 is the primary structure which holds the opposing pieces of wood in the desired opposing relationship – it is the dowel which fixes the wood as desired – and the side spurs 1 serve to prevent withdrawal of the dowel. Further, as noted by *Harrild* at lines 24-29, the center piece 2 is necessary to allow the spurs 1 to be successfully driven into wood without damage, and thus an ordinary artisan would not contemplate removal of the center piece 2. See MPEP 2143.01 at Section V (“The Proposed Modification Cannot Render The Prior Art Unsatisfactory For Its Intended Purpose”).

5. Section 7 of the Office Action: Rejection of Claims 51, 53, 55-61, 63, 70, 73, and 79 under 35 USC §102(e) in view of U.S. Patent 6,994,713 to Berg

These rejections were previously made in the Office Action of May 29, 2007, and the rejections were overcome in view of the comments in the Response of November 29, 2007. Since those comments still clearly illustrate how the claims are not anticipated by *Berg*, the rejections should be withdrawn. To review, *Berg* describes a connector (or plug) structure whose primary characteristics are described at column 2 lines 3-35, and are shown in FIGS. 4-5:

These and other objects of the invention are accomplished in accordance with the principles of the invention by providing a connector or plug structure preferably formed by starting from a tube of highly elastic material such as nickel and titanium alloy (nitinol) metal. Each end portion of the tube is cut substantially axially at numerous locations spaced circumferentially around the tube to produce a plurality of fingers that extend substantially axially from each end of a remaining medial portion of the tube. The fingers at each end of the medial portion are then deflected so that

they extend substantially radially out from the medial portion, and the fingers are set (e.g., by a heat treatment) in that deflected condition. For use of the structure as a graft connector, the medial portion is attached substantially coaxially to an end portion of a graft conduit. For use of the structure as a plug the medial portion of the tube is filled with a suitable plugging material or structure.

To install the graft connector or plug in a patient the fingers at each axial end of the medial portion may be elastically deformed back toward their initial condition (in which the fingers extend substantially axially from the ends of the medial portion). The structure may then be inserted in a delivery tube, which may maintain the fingers in their substantially axially extending condition. The delivery tube may then be inserted through the aperture in the side wall of the patient's tubular body conduit to which the end of the graft conduit is to be attached, or through the aperture in the patient's tissue structure that is to be plugged. The delivery conduit may then be removed from around the connector or plug structure. This releases the fingers at each end of the medial portion to spring out on respective opposite sides of the tissue structure to which the connection is to be made, or to which the plug is to be applied.

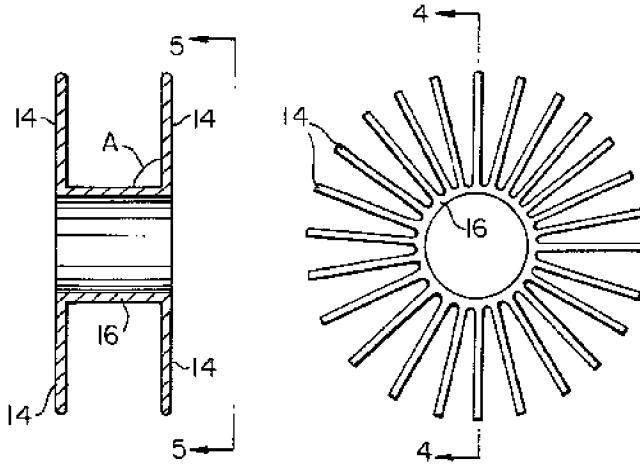


FIG.4

FIG.5

Installation of the *Berg* connector is then shown in FIGS. 7-8 and discussed at column 6 line 58 onward. A hole is cut in a vessel, and the medial portion 16 is then inserted in the hole with one of the sets of fingers 14 grasping one side of the vessel, and the other set of fingers 14 grasping the other side of the vessel:

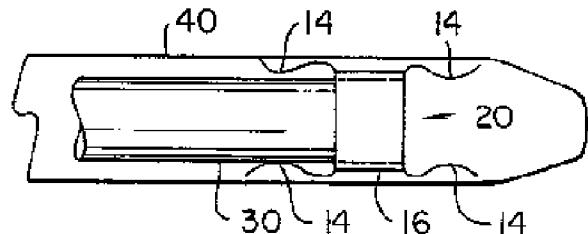


FIG. 7

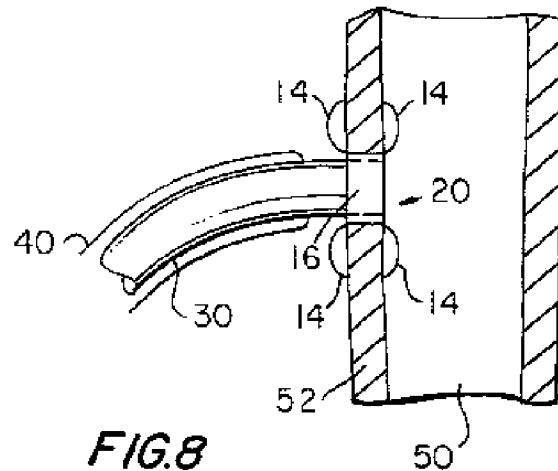


FIG. 8

FIG. 13, discussed at column 7 line 28 onward, shows that the medial tubular portion 16 of the connector can be perforated:

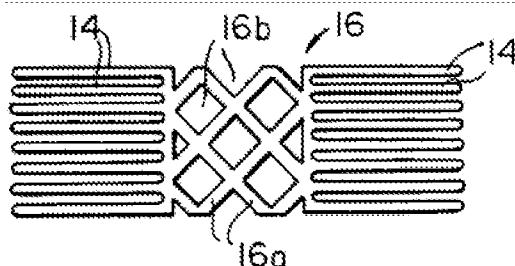


FIG. 13

FIG. 14, discussed at column 8 line 20 onward, describes how the ends of fingers 14 may be sharpened to penetrate tissue.

FIG. 15, discussed at column 8 line 27 onward, shows a connector 20 wherein one of the sets of fingers 14 is elongated and bears a barb 14b so that it may pierce a vessel wall.

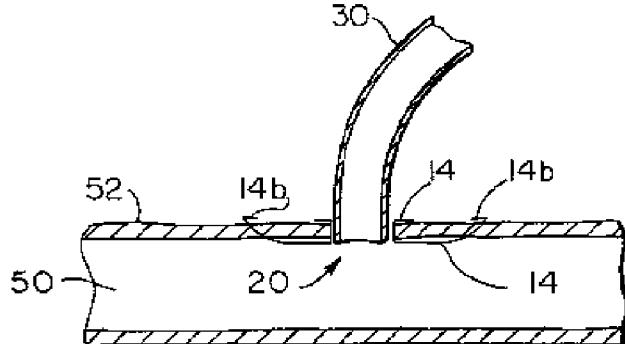


FIG.15

FIG. 18, discussed at column 9 line 15 onward, shows a connector wherein the fingers 14 are "cylindrically curved" so that the tips of one of the sets of fingers 14 curve towards the tips of the other set of fingers 14.

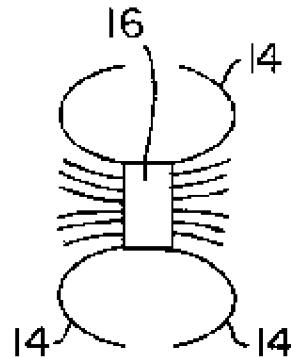


FIG.18

FIG. 22, discussed at column 9 line 25 onward, shows how such a connector may be used to affix a graft adjacent a hole in a wall.

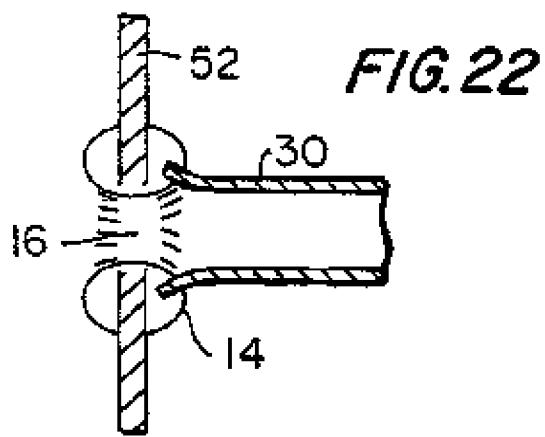


FIG.22

Independent claim 51, at clauses i. and ii., recites that the resilient member has a cross-sectional area at least substantially equal to the greater of (1) the cross-sectional area of the first parts, and (2) the cross-sectional area of the second parts. Looking to FIG. 7 of *Berg* (or FIGS. 10, 11, 19, etc.), wherein *Berg* is shown in its open configuration – or looking to FIG. 3, showing the open connector in full detail – it is seen that *Berg*'s “resilient member” 16 always has a (very) significantly greater cross-sectional area than the first and second parts (the sets of “fingers” 14 on the opposing sides of the “resilient member” 16). Further, it would not be obvious to one of ordinary skill in the art to “shrink” the member 16 to have the same or similar diameter as the collected fingers 14. If this were done, *Berg* would no longer function for its intended purpose of splicing a graft into the wall of a vessel as shown in FIG. 8 of *Berg* (or FIGS. 15, 22, etc.). See MPEP 2143.01 (subsection entitled “The Proposed Modification Cannot Render The Prior Art Unsatisfactory For Its Intended Purpose”). Thus, if the prior art is objectively reviewed without prior knowledge of the invention (i.e., without hindsight), it is seen that the teachings of the art do not lead one to the presently-claimed invention.

Regarding **dependent claim 56**, which recites that the device is formed of one or more wires extending along the length of the device, this structure is plainly not shown or suggested by *Berg*. The Office Action asserts that *Berg*'s FIG. 13 show “the device is formed of and linked together by wires (thin, elongated structures, see fig. 13), but as noted in column 7 line 28 onward (and as shown in FIG. 13), this is plainly not the case: FIG. 13 simply shows a medial tube 16 which is perforated, with fingers 14 extending therefrom. The FIG. 13 device is not shown of wire, nor would an ordinary artisan contemplate forming it of wire.

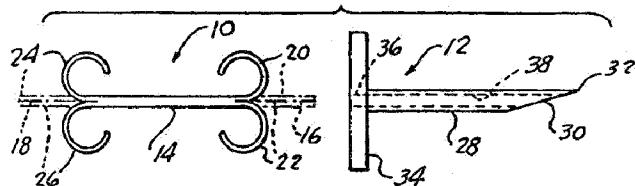
Regarding **dependent claim 61**, which recites that the device is formed of a plurality of wires, as discussed above, this structure is not shown or suggested by *Berg*, nor would one of ordinary skill regard such structure to be obvious in view of *Berg*. *Berg*'s medial tubular portion 16 is not formed of wire, nor is it in any way apparent how *Berg*'s medial tubular portion 16 could be formed of wire with any reasonable expectation of success.

6. Section 8 of the Office Action: Rejection of Claims 51, 64, 67, 74, 75, and 80 under 35

USC §102(b) in view of U.S. Patent 3,527,223 to Shein

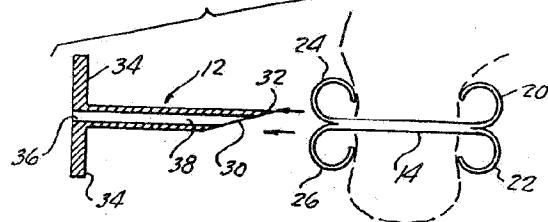
These rejections were previously made in the Office Action of February 19, 2003, and the rejections were overcome in view of the comments in the Response of August 18, 2003. Since those comments still clearly illustrate how the claims are not anticipated by *Shein*, the rejections should be withdrawn. To review, U.S. Patent 3,527,223 to *Shein* does not disclose or suggest the feature of *claim 51* of “at least a portion of at least one of the first and second parts is sharpened to enable said part to pierce a graft and an artery.” Rather, *Shein* utilizes a sharpened hollow insertion needle (12 in FIG. 1) which is used to pierce the earlobe, after which the ear stud 10 can be inserted through the needle 12 (and through the earlobe), with removal of the needle 12 then leaving the stud 10 in place:

FIG. 1.



The first and second parts/ends of *Shein*'s stud 10 are not sharpened, and there would not be any motivation to sharpen them because this would cause pain to the wearer. Consider the effect in *Shein*'s FIG. 5, showing the body 14 of the stud 10 within an earlobe (shown in phantom lines), if the first and second parts/ends of *Shein*'s stud 10 were sharpened: the sharp ends would bear against, and cut into, the earlobe.

FIG. 5.



This is why *Shein* utilizes the separate hollow needle 12. Note that use of such a needle would be disadvantageous for installing a graft in an artery since it would punch a larger hole in the graft and artery wall than is necessary to install the fixator. The end result is that one would have loose (and potentially leaky) fixation. In contrast, the claimed invention may both pierce and fix a graft on an artery with the fixator creating no greater hole than necessary.

The Office Action alleges that the “first and second parts [of *Shein*] are sharpened (inherently along the longitudinal edges of 24, 20, 26, and 22 after “slices” are made at 16 and 18)”. However, this is contrary to common sense – if true, these sharpened edges would slice the earlobe in FIG. 5 above – and more importantly, there is no reasoned statement as to why these edges would necessarily be “sharpened” after being “sliced.” It is not understood why “slicing” the *Shein* stud 10, which is stated to be made of “any suitable plastic, such as polyethylene, or metal, such as spring steel, or stainless steel” (column 1 lines 68-69), would automatically sharpen it, particularly depending on how the “slices” are formed. (For example, note that column 1 line 74 notes how the *Shein* device may be “molded” into the illustrated shape.) As noted in MPEP 2112, Section IV (entitled “Examiner Must Provide Rationale or Evidence Tending to Show Inherency”), it is insufficient to merely allege that an unapparent feature is present in the prior art. Rather, the Office Action must explain how/why the unapparent feature is believed to be present in the prior art. As MPEP 2112 states, “[i]n relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art” (citing *Ex parte Levy*, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990)). The section also states that “[t]o establish inherency, the extrinsic evidence ‘must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.’” (In re Robertson, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999). As then noted in Section V of MPEP 2112, it is only after “the Examiner Presents Evidence or Reasoning Tending to Show Inherency” that “the Burden Shifts to the Applicant to Show an Unobvious Difference.”

Since there is no reasoned statement as to why *Shein*'s first and/or second parts would necessarily be sharpened when they are formed, and since it is clear from *Shein*'s purposes and usage that *Shein* is not in fact sharpened, it cannot fairly be said that *Shein*'s first and/or second parts are inherently sharpened, and the rejections must be withdrawn.

Regarding ***claim 64***, this claim also notes that “at least one of the first and second parts is sharpened”, and thus the comments for claim 51 above are applicable here as well.

7. Sections 10-11 of the Office Action: Allowability of Claim 62

The indication that claim 62 contains allowable matter is noted and appreciated.

8. New Claims 82-84

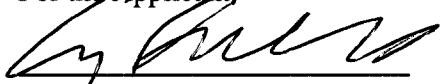
New dependent claim 82 is submitted to be allowable for at least the same reasons as claim 68, from which claim 82 depends. Furthermore, claim 82 is submitted to be allowable for the same reasons as claims 56 and 61, discussed above in Section 5 of this Response.

New dependent claims 83-84 are submitted to be allowable for at least the same reasons as claims 51 and 68, from which these claims depend. Furthermore, these claims further distinguish from the *Shein* reference discussed above in Section 6 of this Response.

9. In Closing

If any questions regarding the application arise, please contact the undersigned attorney. Telephone calls related to this application are welcomed and encouraged. The Commissioner is authorized to charge any fees or credit any overpayments relating to this application to deposit account number 18-2055.

For the Applicant,



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